K123669

APR 0 8 2013

510(k) Summary
for
Sirona Dental Systems
inCoris ZI

1. Sponsor

Sirona Dental Systems GmbH

Fabrikstrasse 31

D-64625 Bensheim

Germany

Contact Person: Fritz Kolle

Telephone: +49 6251 16 3294

Date Prepared: March 05, 2013

2. Device Name

Proprietary Name: inCoris ZI

Common/Usual Name: Powder, Porcelain

Classification Name: Porcelain powder for clinical use

3. Predicate Devices

inCoris ZI (K062509)

4. Intended Use

Classic sintering

- Framework and reduced crowns in the anterior and posterior tooth region
- Bridge frameworks in the anterior and posterior tooth region with max. 2 pontics
- Crown caps in the anterior and posterior region
- Cone and telescoping crowns

Speed sintering

- Framework and reduced crowns in the anterior and posterior tooth region
- Bridge frameworks in the anterior and posterior tooth region with max. 2 pontics and up to 9 units
- Crown caps in the anterior and posterior region
- Cone and telescoping crowns

Super speed sintering

- Framework and reduced crowns with a maximum wall-thickness of 2 mm

5. Device Description and Function

The inCoris ZI are blocks of various sizes from which custom made dental restorations are grinded using Sirona CAD/CAM system. inCoris ZI ceramics constitute blocks comprised of zirconia ceramics (ZrO2). The blocks are initially manufactured in a partially sintered state; then, they are individually processed to specification, and finally, densely sintered. One end plane of a block is mounted to a metal carrier that is inserted in the spindle's clamping chuck of the grinding machine. The blocks are available in different colors.

6. Scientific Concept

The underlying scientific concept is

- Processing dental restorations by Sirona Dental CAD/CAM System
- Restorations are grinded from an inCoris ZI block by a Sirona CAM machine
- Different sintering time to gain appropriate material properties

7. Physical and Performance Characteristics

7.1. Design

The design of the inCoris ZI is described in section 5, Device Description and Function.

7.2. Material Used

inCoris ZI ceramics constitute blocks comprised of zirconia ceramics (ZrO2). One end plane of a block is mounted to a metal carrier that is inserted in the spindle's clamping chuck of the grinding machine. The material is biocompatible according to ISO 10993-1: 2009, "Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process".

7.3. Physical Properties

Final technical data of densely sintered inCoris ZI.

Density:	≥ 6.05 g cm^{-3}
Thermal expansion coefficient (20 - 500 °C):	11.0 10^{-6} K^{-1}
Bending strength:	> 1100 MPa

7.4. Chemical Properties

Component	inCoris ZI
$ZrO_2+HfO_2+Y_2O_3$	$\geq$ 99.0%
Y_2O_3	5.2%
HfO_2	2%
Al_2O_3	< 0.35%
Fe_2O_3	< 0.3%

8. Summary of the technological characteristics

Both, Proposed and Predicate Sirona inCoris ZI are made of zirconia ceramics(ZrO2) and block shaped. Both devices meet ISO 6872: 2008, "Dentistry -- Ceramic materials" and ISO 13356: 2008, "Implants for surgery, Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)". Physical and chemical properties are similar.

9. Nonclinical Testing

Sirona performed a series of tests to assess whether the device is appropriate for the indications for use. Sintering tests coupled with bench mechanical testing highlight that the mechanical properties are appropriate. Furthermore, crack damage inspection, restoration fit, color suitability, and overall usability tests were conducted.

10. Clinical Testing

Clinical tests have not been performed.

11. Conclusion

Based on the comparison of intended use, indications, contra-indications, material properties and processing/fabrication, Sirona Dental Systems believes that the Proposed and Predicate (K062509) Sirona inCoris ZI blocks are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 8, 2013

Mr. Fritz Kolle
Sirona Dental Systems GmbH
Fabrikstrasse 31
Bensheim, Germany D-64625

Re: K123664
Trade/Device Name: inCoris ZI
Regulation Number: 21 CFR 872.6660
Regulation Name: Porcelain Powder for Clinical Use
Regulatory Class: II
Product Code: EIH
Dated: March 5, 2013
Received: March 7, 2013

Dear Mr. Kolle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K123664

Device Name: inCoris ZI

Indications for Use:

Classic sintering

- Framework and reduced crowns in the anterior and posterior tooth region
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Speed sintering

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- Framework and reduced crowns with a maximum wall-thickness of 2 mm

Prescription Use ___X___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
Susan Runner, DDS, MA 2013.04.04 10:34:20 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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